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A Novel Surgical Tool for Stimulation Paddle Delivery to the Dorsal Root Ganglion of the Spine

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A Novel Surgical Tool for Stimulation Paddle Delivery to the Dorsal Root Ganglion of the Spine

by

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Abstract

A Novel Surgical Tool for Stimulation Paddle Delivery to the Dorsal Root Ganglion of the Spine

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Dorsal root ganglion (DRG) stimulation is a novel method of treating chronic pain in which a lead with a set of electrodes is placed on the nerve root of the spinal cord above the pain site. This method shows promise over traditional spinal cord stimulation due to the its localized nature as opposed to stimulating the entire dorsal column. Paddle stimulators have been shown to have more targeted therapy, are more energy efficient, and be more versatile by having a larger number of electrode contacts than traditional cylindrical leads. The major challenge with delivering a paddle electrode is accessing the DRG without damaging the root. This project seeks to create a novel surgical tool to assist in delivering a stimulating paddle into the intervertebral foramen via a stylet-retractor mechanism. The tool has a footprint 50% smaller than the available space through which to traverse to access the DRG and can overcome the estimated 1.7 lb force of the surrounding ligaments. The device obtained positive feedback during cadaver labs with orthopedic surgeons and could be manufactured in the future as a viable product.

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Chapter 1. Introduction

1.1 Background

Overview on SCS

Spinal cord stimulation (SCS) is a common approach to treat chronic intractable back or leg pain which may be linked to a variety of causes, with more severe instances due to failed back surgeries or complex regional pain syndrome (CRPS). CRPS is a progressive disease caused by damage to the peripheral nervous system which can cause pain, swelling, paresthesia. Chronic pain affects the activities of daily living and health-related quality of life. Spinal cord stimulation (SCS) reduces the need for medications and continuous treatments with the use of an electrical implant that stimulates the ascending nerve (a-beta) fibers in the spinal cord dorsal column. It is theorized that stimulation in this location inhibits transmission of pain signals to the brain.[1,2]

Stimulation of the Dorsal Root vs. the Spinal Cord

Percutaneous SCS leads are cylindrically-shaped with 4-8 electrodes used to stimulate the thoracic or lumbar regions of the spine. However, since the dorsal column contains nerves that affect large regions of the lower body, attempts at treating localized regions may not sufficiently reduce pain or may cause paresthesia to a larger portion of the body than the desired treatment area.[1,2] Hence, the dorsal root ganglion (DRG) was considered as an alternative site of stimulation. The DRG contains the primary sensory neural cells, including the ones that transmit pain information to the brain, and thus can be used to specifically target localized regions.

Benefits of Paddle vs. Percutaneous Leads

In addition to the location of lead placement, there are differing benefits and downsides to using cylindrical versus paddle leads. With cylindrical electrodes in percutaneous leads, a large portion of the surface area of the leads are not contacting the nerve root (Figure 1.1). Hence, directional electrodes in paddle stimulators reduce excess electrical output, prevent extraneous

stimulation, and cover a larger proportion of nerve root relative to the area of the lead itself. Examples of these paddle leads can be seen in Figure 1.2. Percutaneous leads also have a higher rate of dislocation and infection compared to paddle leads[3] and, also, require a greater number of surgical revisions.[4]

Figure 1.1: Percutaneous (cylindrical) lead delivered to the DRG

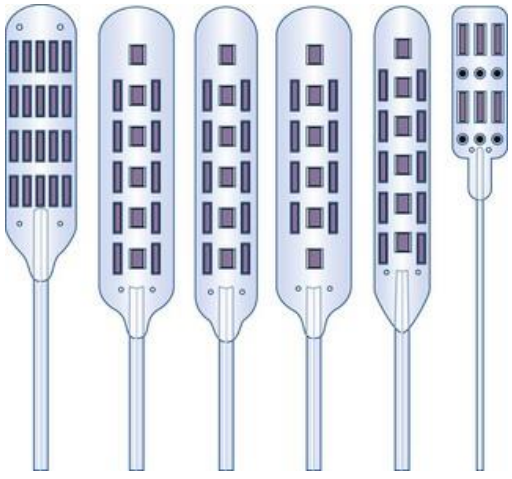


Figure 1.2: Variations of SCS paddle electrodes

Differences in Percutaneous and Paddle Lead Implantation

During a percutaneous lead implantation, the patient is placed prone onto a surgical frame, with the back in flexion. A needle is inserted in the thoracic or lumbar region with the assistance of fluoroscopy, and a cannula containing the percutaneous lead is inserted through the epidural space and guided up the spinal cord to the desired stimulation location. Implantation of a paddle lead involves a more invasive surgery in which the spinal cord must be accessed and a hemilaminotomy must be performed to access the DRG. To minimize the invasiveness and decrease recovery time for the patient, surgeons use a tube dilator to gradually separate the muscles and tunnel towards the surgical site.

1.2 Significance of the Problem

The main challenge of surgical paddle intervention for the DRG is accessing the intervertebral space and delivering the paddle without damaging the nerve root and without the paddle buckling from the surrounding ligament structure. Surgical tools such as traditional forceps or cross-action forceps risk opening and damaging the surrounding nerve root. Hence, a surgical delivery tool that can safely and effectively deliver a DRG paddle is needed for spinal cord surgery intervention.

1.2.1 DRG Spatial Limitations

The major limitation in delivering the DRG paddle is the small volume of space that must be traversed to access the nerve root. The root itself is located under the vertebral pedicle, within a space called the intervertebral foramen. Literature shows that, at least within the lumbar spine, most of DRG is located intraforaminally, though sometimes they may be found intraspinally and extraforamenally.[5,6] Figures 1.3-1.7 were retrieved from the literature for determining the

dimensions of the intervertebral foramen and DRG. The dimensions of this space are critical in determining the size of the tool and amount of room there is to deal with in delivering the paddle.

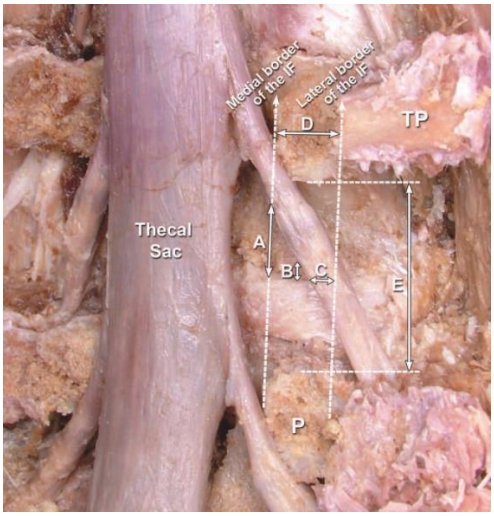


Figure 1.3: Cadaver image of cranial-caudal cross-section of spine showing dorsal nerve root within the interforaminal space[7]

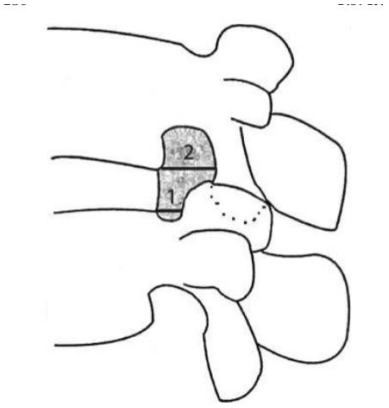


Figure 1.4: Measurements taken at 1) cranial cross-section and 2) caudal cross-section of foramen[8]

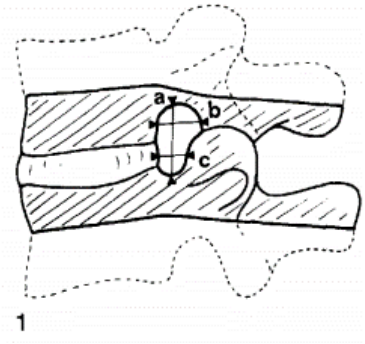


Figure 1.5: Measurements of foramen[9]

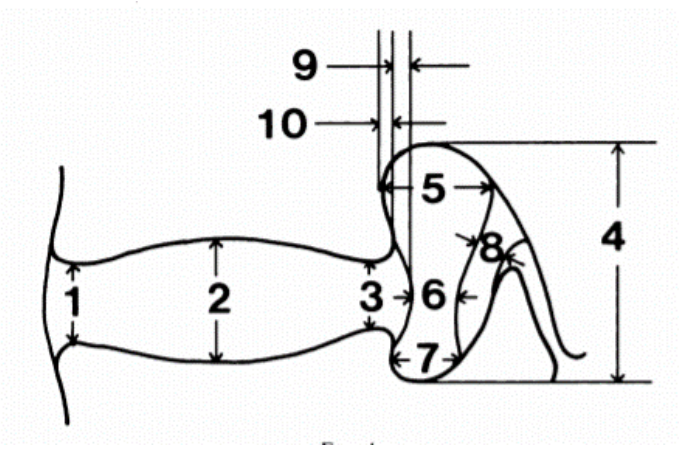


Figure 1.6: Notable measurements of foramen include 4) height, 5) caudal width, 7) cranial width, 8) thickness of ligament[10]

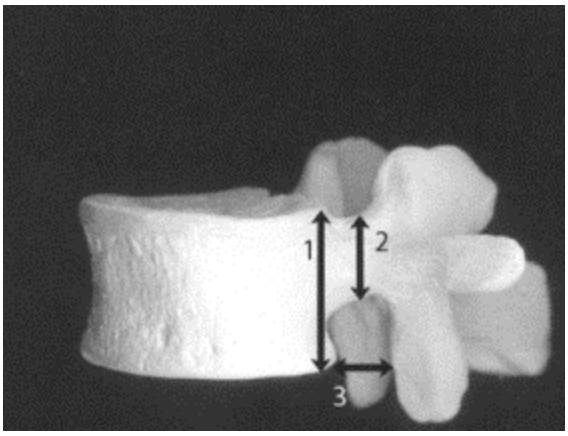


Figure 1.7: Measurements of foraminal height (1-2) and width (3) taken from skeletal data[11]

Tables 1.1-1.3 consist of the accumulated literature review on foraminal space, DRG sizing, and ligament forces that need to be overcome. The data for foraminal height, width (caudal), width (cranial) and DRG height and width are consistent and can be used to determine the special limitations of the surgical area.

Source	Dimension (mm)	Average	L1-L2	L2-L3	L3-L4	L4-L5	L5-S1
Mayoux-Benhamou[9]	Height	14.2					
	Width (caudal)	6.9					
	Width (cranial)	3.5					
Sohn (cervical)[12]	Height	11.08 ± 1.88					
	Width	5.69 ± 1.91					
Lentell (cervical)[13]	Height	10.6 ± 0.8					
	Width	7.2 ± 0.6					
Arslan[7]	Height	20.8 ± 0.9	20.8 ± 1.4	21.5 ± 1.6	21.2 ± 1.5	21.2 ± 1.5	19.3 ± 1.4
	Width	12.9 ± 3.6	8.3 ± 1.3	11.1 ± 1.3	12.5 ± 1.6	14.6 ± 1.8	17.8 ± 1.8
Ruhli (and Henneberg*)[8,11]	Height (caudal)*	7.4 ± 1.2					
	Width (caudal)	11.9 ± 1.7	13.3 ± 0.3				10.6 ± 0.8
	Width (cranial)	7.9 ± 1.3				6.7 ± 0.4	
Hasegawa[14]	Height	20.51 ± 0.73	19.97 ± 2.24	21.20 ± 2.56	21.41 ± 3.02	20.07 ± 2.75	19.89 ± 3.99
	Width (caudal)	8.89 ± 0.69	7.77 ± 1.32	8.82 ± 1.28	9.14 ± 1.39	9.08 ± 1.76	9.63 ± 1.98

Table 1.1: Intervertebral foramen dimensions

Source	Dimension (mm)	Average	L1	L2	L3	L4	L5
Shen[6]	Width	5.10 ± 1.18	3.38 ± 0 .77	4.51 ± 0.88	5.37 ± 0.96	5.83 ± 0.94	6.40 ± 0.91
	Length	7.52 ± 2.77	4.35 ± 0.89	5.85 ± 1.11	7.20 ± 1.36	8.64 ± 1.49	11.58 ± 2.25
Hasegawa[10]	Area (mm^2)	34.40 ± 4.57	28.31 ± 10.48	32.08 ± 8.9	36.84 ± 12.07	34.48 ± 11.25	40.31 ± 12.38
Kobayashi (cervical)[15]	Width	6.17 ± 0.38					
Hasegawa[14]	Width	5.2 ± 1.0	3.7 ± 0.7	4.6 ± 0.7	5.7 ± 0.7	6.2 ± 0.7	5.9 ± 0.7
Hasegawa[14]	Height	6.7 ± 1.7	4.3 ± 0.9	5.6 ± 1.2	7.3 ± 1.4	8.2 ± 0.9	8.3 ± 1.2

Table 1.2: DRG dimensions

Source	Dimension	Average	L1-L2	L2-L3	L3-L4	L4-L5	L5-S1
Hasegawa[10]	Thickness	3.76 ± 0.19	3.84 ± 0.78	3.94 ± 1.06	3.9 ± 1.13	3.63 ± 0.76	3.49 ± 0.76
Lin[16]	Force (N)	7.5					
Tran[17]	Force (N)	6.0 ± 3.0					
Naemura (porcine)[18]	Force (N)	5					

Table 1.3: Ligament dimensions

It is also important to note the ratio of the cross-sectional area of the root to the cross-sectional area of the foramina is higher at inferior disc levels (Hasegawa), meaning there is less space to maneuver within the lower vertebrae.

From the literature review, the average height of the foramen is calculated to be 15.4 mm ± 5.0 mm (0.6 ± 0.2 in) and average width is 8.9 ± 2.9 mm (0.4 ± 0.1 in). The average width of the DRG is calculated as 5.5 ± 0.6 mm (0.22 ± 0.02 in). Hence the limiting direction (width), along with the thickness of the DRG, gives a space of approximately 3.3 mm (0.13 in).

With all this in mind, the maximum height of the tool with the paddle should not exceed 3.3 mm (0.13 in). The existing paddle design has a thickness of 0.457 mm (0.018 in). It is important to consider the thickness of the delivery tool and any modifications to the paddle when designing a solution.

1.2.2 Ligament Structure and Forces

The ligamentum flavum (LF) is a set of elastic tissue that travels longitudinally along the spinal cord and connects the vertebrae near the dorsal side at the facet joints (Figure 1.8). It consists of 80% elastin and 20% collagen[19] and is the strongest ligament in the spine. The thickness of the ligament structure increases further down the spine. The deep component of this tissue is the main barrier to accessing the DRG and must be pushed through with the delivery tool to provide access for the stimulating paddle.[20]

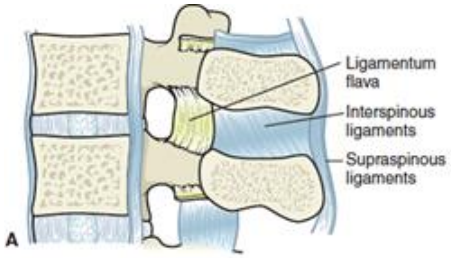


Figure 1.8: Ligamentum flava as seen in a sagittal view[21]

Literature data places the force of the LF at a maximum of 7.5 N (1.7 lbf) as determined from force resistance tests using an epidural needle.[16,17,18] The thickness of the LF can range from 2.7 - 5.6 mm depending on if the if the patient's spine is normal or has confounding medical issue like spinal stenosis or herniated disk.[10,19]

Studies of the thoracic vertebrae indicate there are also numerous transforaminal ligaments near the DRG as it exits the foramen (Figure 1.9).[22,23] These ligamentous bands may not be seen in all levels or even on both sizes of the vertebrae.

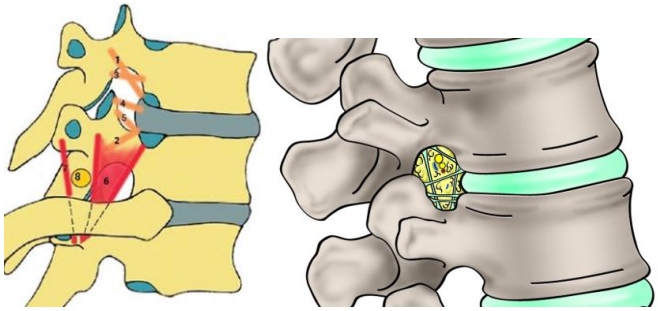


Figure 1.9: Picture of the ligaments within the foraminal space[22,23]

1.2.3 Surgical Technique

The surgical procedure for delivering the paddle electrode consists of using fluoroscopy to determine the location of midline incision, then cutting through the skin, fat, ligaments, and epidural space. Tube surgery is often conducted, so the tool must not be wider than the inner diameter of the tube (typically around 3 inches). A hemilaminotomy (Figure 1.10) consists of cutting part of the lamina to access the DRG, while hemilaminectomy consists of removing the spinous process altogether. The recommendation is to access DRG through cranial side of vertebra below the desired delivery site and travel upwards to the nerve root. The radiopacity of the metal electrodes in the paddle allow for precise alignment and adjustment as needed during the procedure.

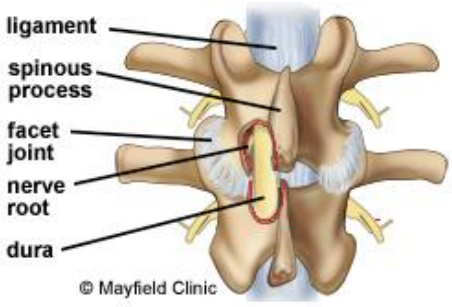


Figure 1.10: Hemilaminotomy (dashed red line) performed on the caudal side of the lamina on the top vertebra and cranial side of the lamina on the bottom vertebra

From the analysis of DRG space and limitations, it is recommended that the surgical procedure remove bone in the cranial side of the vertebra below the desired DRG delivery site and access the DRG from below. This will allow for maximal foraminal height through which to traverse and access the DRG.

Chapter 2. Design Process

The design process consisted of research on currently-used surgical tools that could be used to solve the problem, brainstorming tool designs, and narrowing down to the chosen design concept.

2.1 Design Research: Existing Surgical Tools

Looking at existing surgical tools provides insight into the expectations of the surgeon for a future tool design. This analysis goes through a few possible ideas that a future tool could be modeled upon and reasoning why they may not work in their current form to solve the problem.

Forceps

Surgical forceps are mechanical tools that rely on a hinge mechanism to open and grasp an object for implantation (Figure 2.1). Typically, these forceps are made of medical-grade carbon steel and can easily be sterilized for reuse. They come in differing forms. Some are similar to tweezers, relying on spring action to keep the tweezers open by default. Another form is called the Kelly hemostatic forceps which resemble scissors in that they are grasped via two finger holes at the proximal end and have a serrated surface at the distal end to clamp blood vessels or suture needles. At the proximal end they have a ratcheting mechanism to lock the tips in place. This locking mechanism would be desirable in a paddle delivery tool to allow the surgeon to maneuver through the intervertebral space without risk of losing the paddle before placement. However, the lack of control in range of motion when opening the forceps deem them an undesirable tool for this purpose because of the risk of damaging the nerve root.

Figure 2.1: A pair of Kelly hemostatic forceps

Cross-Action Forceps

Reverse-action or cross-action tweezers or forceps apply the same concept of spring-loaded tweezers or forceps, but they remain closed in the default position (Figure 2.2). They are often serrated for grip strength and made of stainless steel. Pinching the tweezers in the proximal end opens the tips allowing for controlled release of an object with a predictable range of motion. This mechanism would be more acceptable when maneuvering through the intervertebral foramen; however, it still requires a greater volume of space to work relative to the size of the paddle itself, and thus may not be the absolute best mechanism to release the paddle over the DRG.

Figure 2.2: A pair of reverse-action tweezers

Penfield elevator

A penfield elevator is a surgical tool that is in the family of dissectors and come in five different shapes (Figure 2.3). It can be used to manipulate tissue, scoop up bone, and dissect tissue. They come in varying curvature angles and shapes in the tips. A penfield elevator can be used in conjunction with a modified paddle containing a pocket in the back. Previous cadaver experiments showed that the penfield tip is not long enough to provide support along the entire posterior surface of the DRG paddle, causing the paddle to buckle when inserted into the foramen. It also does not have a release mechanism for the paddle besides relying on friction to allow the ligaments to catch onto the paddle and allow the tool to be removed. However, feedback from surgeons expressed the desire for a similar tip angle for easier maneuverability in the foramen. There was also good feedback about the "pen-like" nature of the tool, which will be shown to be incorporated into the final design.

Figure 2.3: Penfield 2 elevator used for tissue manipulation and bone dissection

2.2 Design Process

2.2.1 Brainstorming and Design Selection

Design brainstorming sessions consisted of open ended discussion-style meetings in which any and all ideas for delivering the paddle were on the table. The solutions could modify or not modify the paddle stimulator itself. Below are the ideas selected during the design process and the reasoning behind choosing the current design.

Cranial-caudal forceps

The first design concept considered were cranial-caudal forceps (Figure 2.4). Cranial-caudal forceps would incorporate the design of cross-action forceps with longer tip ends and a controlled opening range to minimize expansion into the foraminal space. After initial prototyping, the major downside with this design was the difficulty prototyping the tool with 3D printed ABS material, which caused it to be more flimsy and not have the required spring force for functionality.

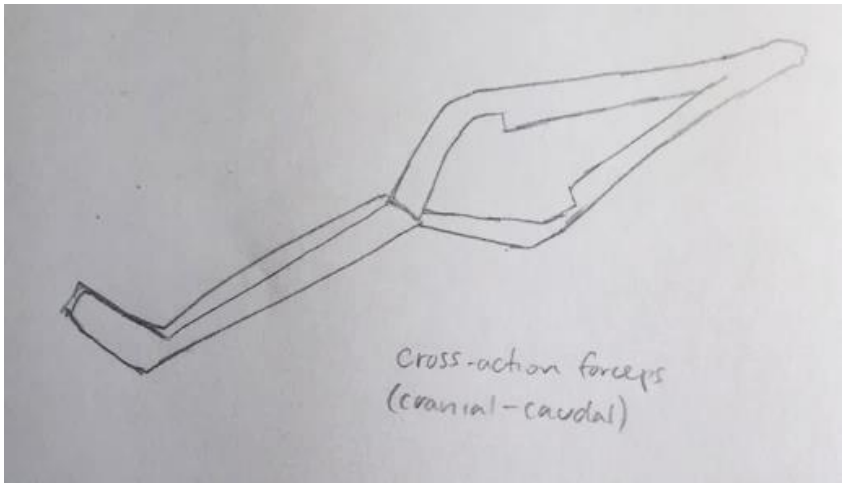


Figure 2.4: Brainstorming sketch of cranial-caudal forceps

Lead blanks

Orthopedic surgeons consulted for the project expressed positive feedback at the idea of a lead blank, or a stiffer version of the paddle lead, either made of CarboSil sheets, injection molded silicone, or ABS for prototyping to clear the ligamentous space and make room for the stimulating paddle (Figure 2.5). The idea stemmed from placing multiple paddles within the same region and noticing that placement after the second or third time became easier with repeated delivery. This design is a possible future option, but the downsides are that it would require time for multiple insertions and accuracy for insertion into the cleared out orifice with the paddle the second time, or else the paddle will buckle.

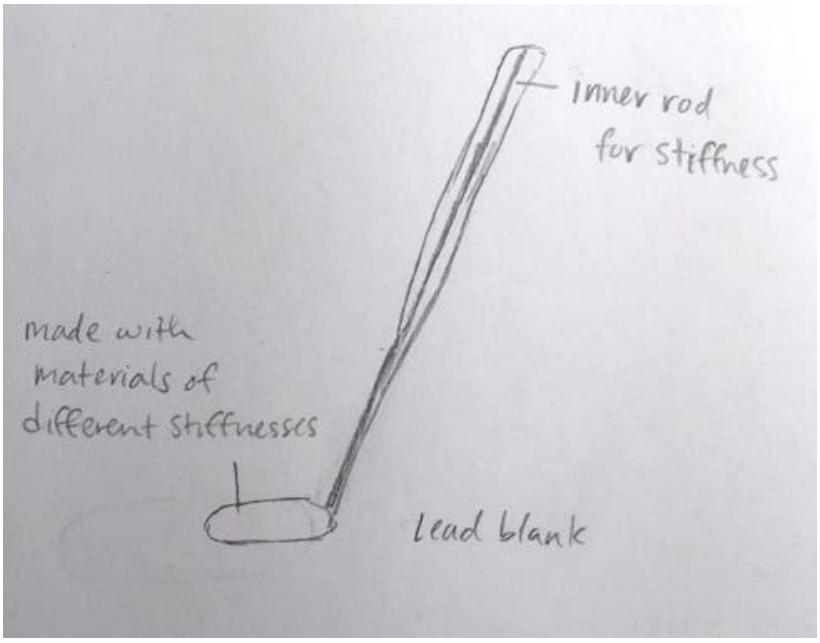


Figure 2.5: Brainstorming sketch of lead blank

Suction tool

The team considered a suction tool as a potential solution (Figure 2.6). This tool would have a roof over the paddle to help guide it through the foramen and would be

connected to a tube that would provide suction to allow the paddle to stay close to the roof of the tool during delivery. The paddle would then drop when suction was removed. The downsides to this device idea is the inability to ensure a good seal for suction and the need for additional equipment to provide suction. It would be interesting to see if this tool could be used as an attachment for traditional fluid suction in the operating room.

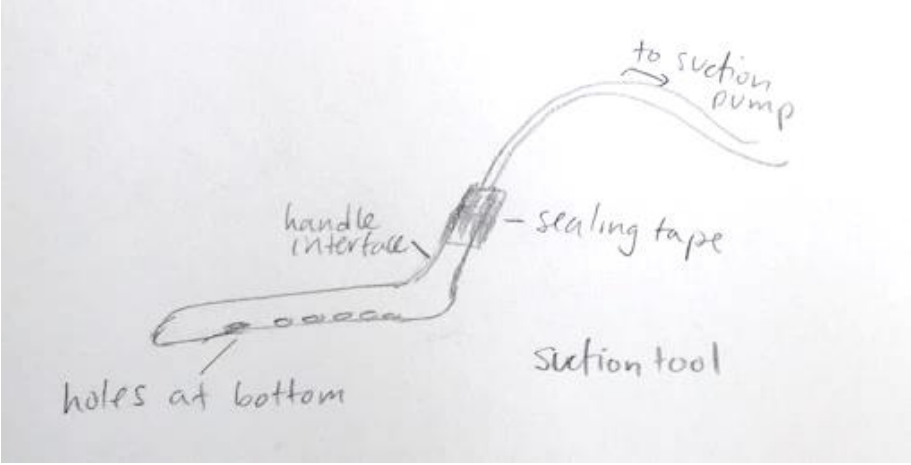


Figure 2.6: Brainstorming sketch of suction tool

Stylet-Delivery Tool

The final design that was considered incorporated a stylet to deliver the paddle. The stylet delivery tool would consist of an outer tube with a slot cut at the tip for the paddle (Figure 2.7). A stylet is inserted through the tube, passes through a pocket manufactured to the top of the paddle, and re-enters the tube tip. The paddle is inserted via the stylet into the foramen and then the stylet is retracted to release the paddle in place. A handle attached to the tube allows for easy maneuvering and a button retracts the stylet manually or automatically with a spring. This design was selected for further prototyping due to its small footprint and ability to possibly overcome the ligament forces to deliver the paddle.

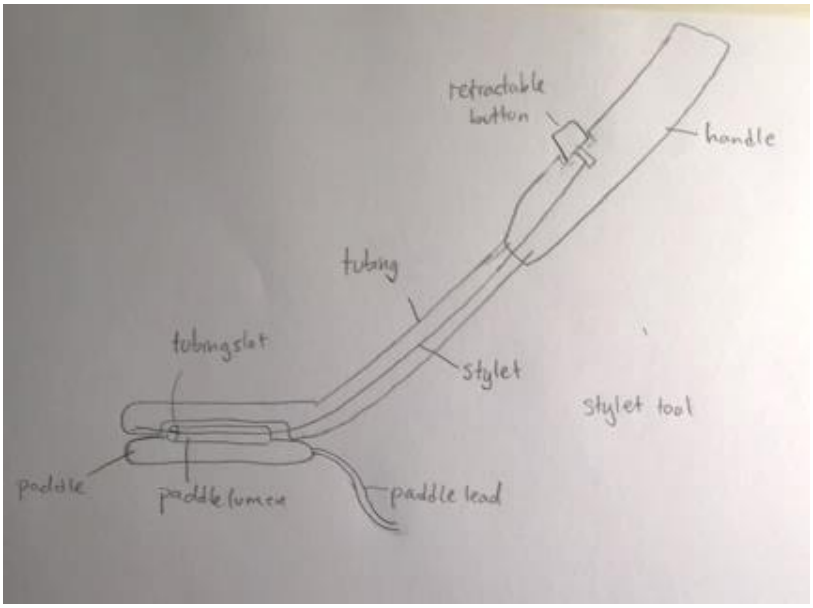


Figure 2.7: Brainstorming sketch of the stylet-delivery tool

2.3 DESIGN PROTOTYPING

2.3.1 Paddle Modifications Needed for Surgical Tool

Currently the electrical paddle is composed of CarboSil sheets with platinum iridium electrodes molded together with a Carver press. Further information cannot be divulged on the paddle design, but it is important to understand that modifications are needed to allow a stylet to be inserted onto the top of the paddle for delivery with this tool design.

2.3.1.1 Paddle Lumen

In order to allow the stylet to enter the paddle, an additional lumen is added to the top of the paddle (Figure 2.8). CarboSil ® 20 90A Biocompatible Silicone Polycarbonate Urethane (ASTM D792) is a thermoplastic with a melt flow of 224°C/2160 g and hardness

of Shore A. It is chosen because of its high tensile and flexural yield strength, which is needed for its application onto the curved surface of the DRG.

The paddle is made in a series of compression molding steps with heat and pressure to reflow the CarboSil together. The final step is creating the lumen for the stylet to pass through. Initial attempts included 0.01" Bionate tubing, but this did not reflow well with the CarboSil, preventing a smooth fillet from being formed between the lumen and the paddle. Bionate also causes the paddle to be stiffer than desired for surgical use in the DRG. Ultimately, the lumen is added by placing a shaped sheet of 0.010" CarboSil with a 0.035" diameter metal rod between the sheet and the rest of the paddle. The setup is placed onto a mold, with the lead body sitting inside a channel at the bottom of the mold to prevent it from interfering with the stylet lumen. A piece of silicone rubber with a carved channel on top is placed between the top CarboSil layer and the top of the mold to help the CarboSil to flow evenly. Table 2.1 shows the information regarding the Carve press used in the molding process. The top layer is molded using two steps of 250^{o} with no pressure for 3 minutes to allow for CarboSil reflow, then 250^{o} with 100lb pressure for 1.5 minutes for forming the lumen. After the paddles with lumen are created, an unheated hydraulic press is used along with a cutting mold to cut out the final desired shape of the paddle.

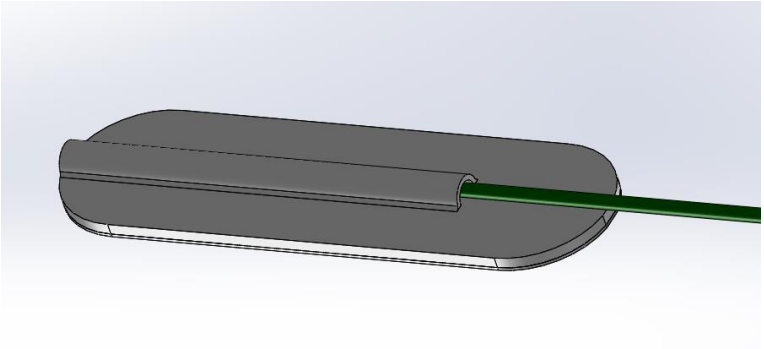


Figure 2.8: Paddle with added lumen to allow for stylet (green) to pass through

Carver Press Model #	#2086/Model C
Platen Size	6”x6"
Heated Platens thermostat control	2102.1 (115V) steel (150-500o F)
heated platens digital control,	steel to 650oF (115V)
cooling platens	2104 aluminum with valve and hose assemblies
Digital Control assembly	Model # 3984 6x6" hot plates (115V)

Table 2.1. Carver press model information

2.3.1.2 Benefits and Downsides of Paddle Design

The CarboSil lumen channel provides the paddle with additional stiffness along the middle without compromising the overall flexibility which could help with insertion into the foramen. Additionally, after the stylet is removed, the entry into the lumen could provide a location for tissue ingrowth to prevent dislocation of the paddle. On the other hand, adding the lumen requires an additional processing step. There is also a risk that a sharp end of the stylet could pierce the closed end of the lumen, potentially damaging the nerve root during insertion. This risk can be mitigated by having a thicker piece of CarboSil at the closed end, or by adding an additional silicone cap to block the stylet from exiting the lumen.

2.3.2 Surgical Tool Design

The initial design was inspired by an existing product used to insert the burr hole cap for DBS implants. SolidWorks 2016 was used to create initial design concepts. The design consists of an ergonomic handle with a screw-on end cap. The handle has a path for a button to travel for inserting and retracting a 0.017” stainless steel stylet with a PTFE

lubricious coating (ISO 13485). The stylet is glued to the retractable button with UV glue. The tubing was made of 0.55 inch diameter Bionate 55D. The desired length of the tubing was determined by an estimated depth of skin, fat and tissue from a study that showed that males with an average BMI of 23.9 had a depth of 1.78 inches from skin to the subarachnoid space of the spine.[21] The final length of the tubing was determined to be 2.3 inches. The tip length was 0.3 inches and an additional 0.22 inches was added to allow the surgeon to maneuver further away from the body and approach at different angles if necessary. For this design, the tubing curved 90 degrees at the tip. The initial idea had a tip design with a slot for the stylet to exit the tubing, enter the paddle lumen and re-enter the tubing on the other side (Figures 2.9 and 2.10). This design was beneficial because it allowed for a protective end cap to enter the ligaments of the foramen first while delivering the paddle.

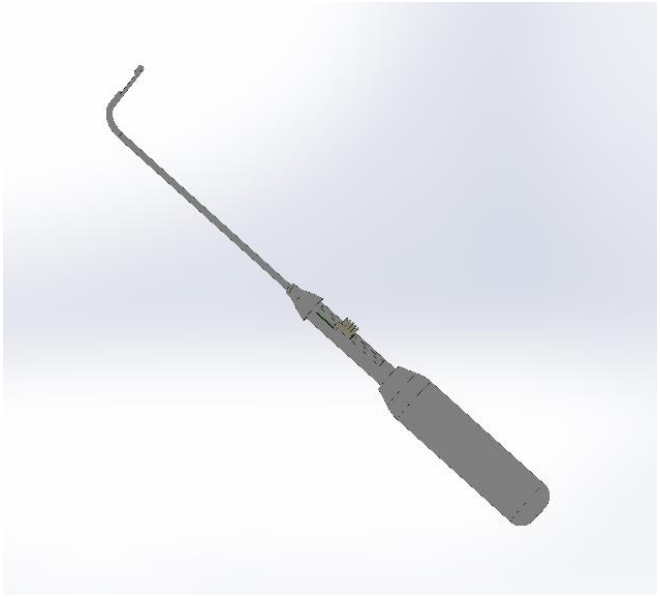


Figure 2.9: CAD model of initial design prototype

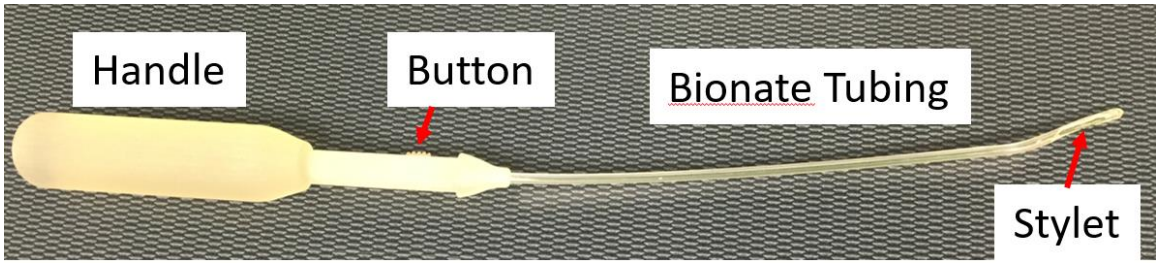


Figure 2.10: Initial design prototype of stylet-delivery tool

After feedback, it was determined that the handle was larger than the desired size for surgeons, who use thin surgical tools gripped with their fingers in a supine position instead of a prone full-handed grip. There was also feedback that the tip end was too large for the space and the tool experienced greater interference and deflected in the space. This could be a combination of the tip diameter as well as not enough stiffness in the tubing.

The second iteration benefitted from a thinner, more pen-like handle to accommodate how surgeons hold their instruments (Figure 2.11). The design was still manually retractable along the body of the handle. The travel was 0.353 inches, the length of the paddle. The design was updated to have a 1/16 inch brass cylindrical tube inside a 3/32 inch brass rectangular tube for extra strength. The tip end was eliminated from the design and the stylet simply exited the tubing and entered directly into the paddle lumen (Figure 2.12). The cylindrical tubing was inserted into the rectangular tubing at the curve of the tip and bent together for forming.

Figure 2.11: CAD model of second iteration prototype consisting of a pen-like handle.

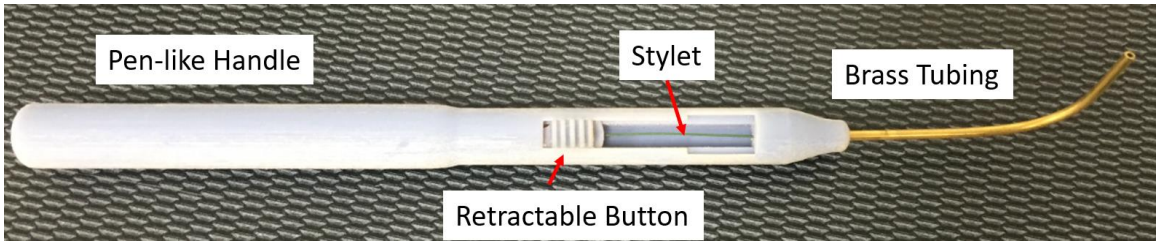


Figure 2.12: Prototype of pen-like tool

After further testing, the stylet simply exiting the tubing did not provide enough stiffness for the paddle to not bend from axial forces. Hence, the rectangular brass tubing was modified and cut to create a roof over the paddle. The final iterations of the design consisted of a 3.27 lb load spring to allow for automatic recoil of the stylet and a relocking mechanism. The handle of the tool had to be widened to accommodate for the commercially-bought spring, but final designs can utilize a smaller spring to be used with a thinner handle. The initial prototype for the automatic retraction design had a spring that fit in the front cap (yellow in Figure 2.13). The linear actuator button (green) would be

pushed down and the spring would force it to slide back. A small tooth on the back of the actuator would then catch onto a hole on the inside of the handle (red) and stop the retraction motion. This prototype experienced failure due to the button not having enough stiffness to stick out of the handle, which can be attributed to the weakness of the ABS material used (Figure 2.14).

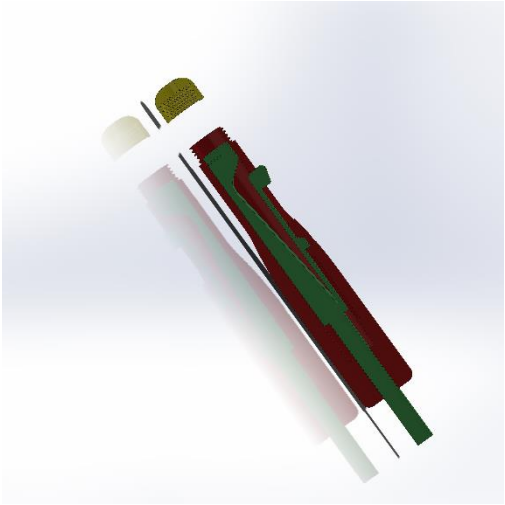


Figure 2.13: CAD model of first design of automatic retractor mechanism

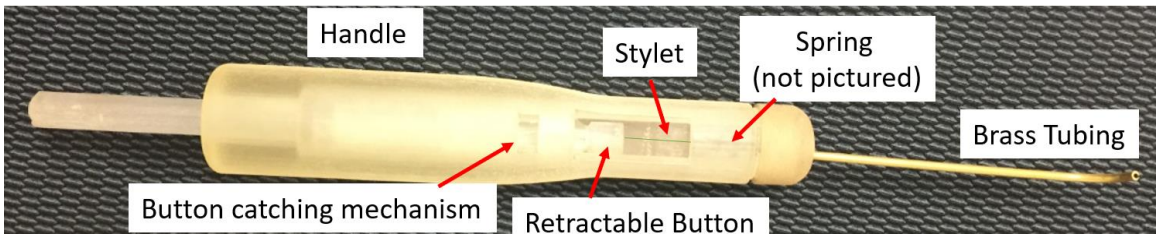


Figure 2.14: Prototype of initial retractable button design

The final design required a path cut into the body of the handle to allow for a mechanical linear actuator button to be inserted. The downside to this design is the cut

made in the threaded region of the handle. This can be avoided in the future with a processing technique that created the handle in separate halves and combines the assembly using snap fits. The angle of curvature was reduced to 28 degrees (arc length 0.6 inches, radius of curvature 1.23 inches) to accommodate the incident angle of insertion by the surgeons. The relocking mechanism utilized an actuator that is restrained by a lip on the top of the handle. After the paddle has been deployed, the user simply pushes the relocking button to the right and the spring pushes the actuator back along the cut path, retracting the stylet, delivering the paddle in place. The final design can be seen below in Figures 2.15 and 2.16. A cost analysis can be seen in Table 2.2, with 3D printing costs being negligible since the equipment is already available. Detailed CAD drawings containing dimensions can be found in Appendix A along with a Bill of Materials (BOM).

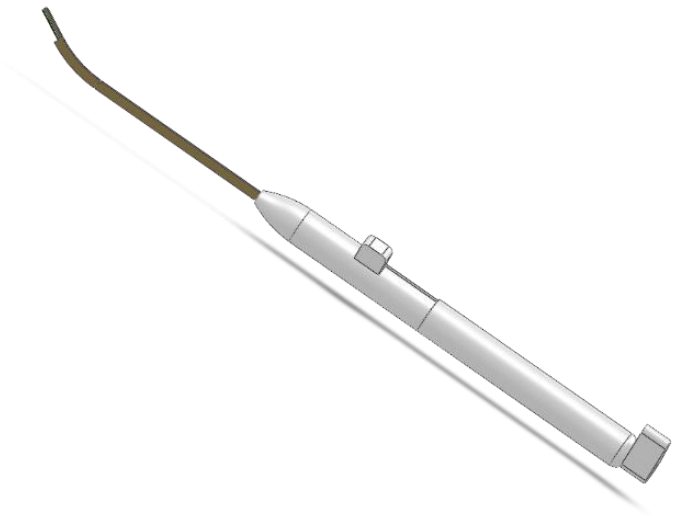


Figure 2.15: CAD model of final DRG surgical tool design

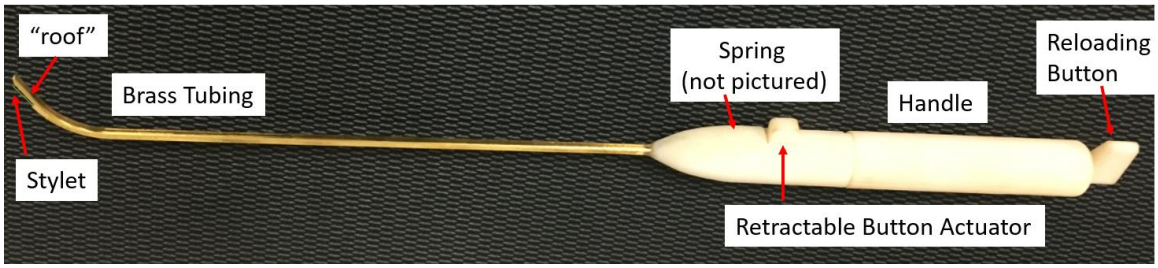


Figure 2.16: Prototype of final tool design

Part	Part Name	QTY	Material	Processing	Price Per Unit
1	Handle Front	1	ABS	SLA	$0.085 [25]
2	Handle Actuator	1	ABS	SLA	$0.085 [25]
3	Handle Back	1	ABS	SLA	$0.085 [25]
4	Reset Button	1	ABS	SLA	$0.011 [25]
5	Stylet	1	Stainless Steel	OEM Component Supply CGWX-0170	$3.36 [26]
6	Tubing	1	Brass	OEM K & S Engineering 100131 & 104158	$1.70
7	Spring	1	Zinc-Plated Steel	OEM McMaster 9657K269	$0.88 [27]
				3D Printing Costs	$0.01
				Total Cost	$6.22

Table 2.2: Current prototype costs

2.3.3 Dimensional Limitations Overcome

Overall, the thickness of the paddle-tool system was defined as follows:

Paddle thickness with lumen: 0.042 in

Tubing roof thickness: 0.030 in

Overall thickness: 0.072 in

This thickness is well below our limiting intervertebral space between the bone and DRG of 0.13 in, with a safety factor of 1.8.

Chapter 3. Conclusion

3.1 Summary of Work

To summarize, after conducting a literature review of DRG and intervertebral foramen dimensions as well as ligament forces, a prototype was created for a surgical delivery tool that can effectively deliver a stimulating paddle without damaging the surrounding nerve root and with the ability to overcome the force of the ligaments. Modifications to the paddle were made to add a lumen on the back for the insertion of a stylet during delivery. The tool itself is made of a handle with a retractable actuator, a stylet wire, and tubing to guide the stylet as well as provide stiffness when being inserted into the ligaments of the foramen.

3.2 Future Work

Future iterations will require the handle to be designed with two separate halved parts bonded together with epoxy. Table 3.2 shows a cost and materials selection table for the final manufactured version of the tool. Separating the handle into two parts will allow for easier manufacturing with injection molding. The tubing will be made of medical grade stainless steel (Hardness 70 Rockwell B, Yield Strength 215 MPA).[28] Literature data states that the estimated ligamentum force is 7.5 N,[16] which can be overcome with the stainless steel tubing with 0.0056 mm deflection from Solidworks Simulation FEA analysis (Figure 3.1).

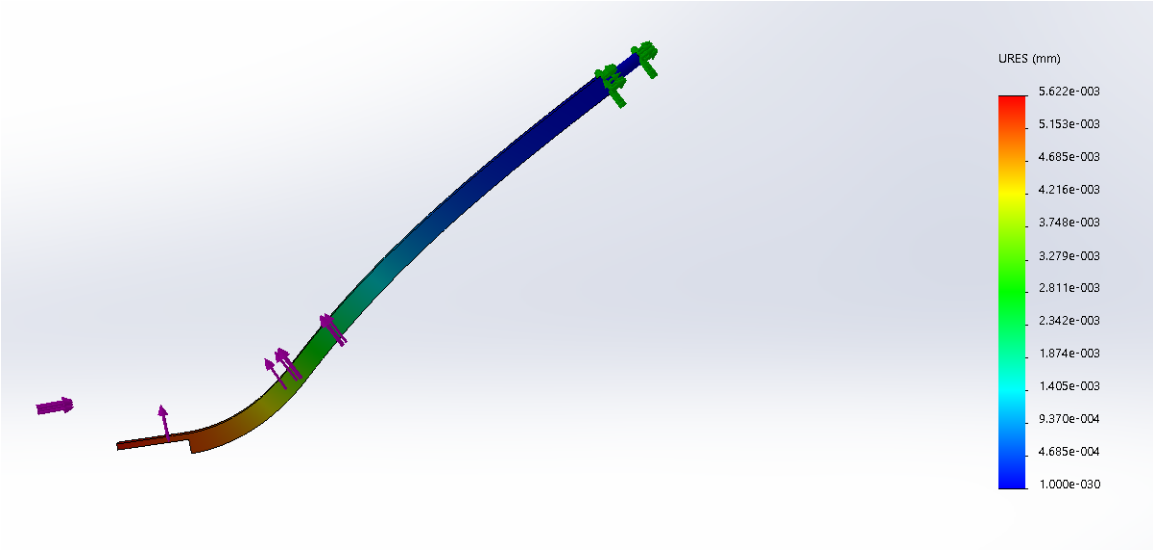


Figure 3.1: FEA analysis for deflection of stainless steel tubing in final device

Other concerns to take into consideration is designing a better button for linear retraction. Currently, for simplicity of assembly, the button requires the user to turn and retract, causing the stylet to turn in place as well. This would cause an issue if the stylet exited from the roof of the tubing or pierce the paddle lumen. A better mechanism would be a linear retraction as seen in Figure 3.2. The button is pushed at the top and then a spring would allow it to travel until it catches on a slot in the handle.

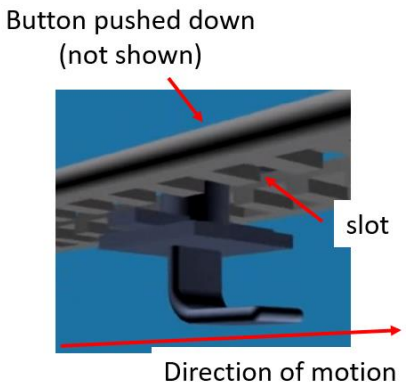


Figure 3.2: Future button design idea for linear motion and “catching” mechanism.

Spinal Cord Stimulation takes up 70% of the neuromodulation market with a $3.65 billion market share in 2015.[31] PEEK is a biocompatible "medical grade" thermoplastic, and the most ideal processing method is injection molding. The cost of future machining includes material cost, tooling for injection molding, equipment costs, and other overhead costs. Other considerations like bending the tube and forming the stylet curve should be addressed in manufacturing as well.

$$Tooling\ cost = \frac{C_T}{n} ceil(\frac{n}{n_T} + 0.51) \quad (1)$$

Where, C_T = tool cost = $3,000

n = 10,000 parts

n_T = tool life (in parts) = 1E6 parts

$$Equipment\ cost = \frac{C_C}{t_{wo} L \dot{n}} \quad (2)$$

Where, C_C = Equipment "Capital" Cost = $30,000 [note: company may already have equipment for other devices within the neuromodulation product line]

t_{wo} = "write-off time" = 5 yr

L = time load = 0.33

$\dot{n}$ = production rate (parts/hr) = 200 hr^{-1}

$$Overhead\ cost = \left[\frac{C_{op}^{tot}}{L} + C_{op}^{prod}\right]\frac{1}{\dot{n}} \quad (3)$$

Where, C_{op}^{tot} = cost/operation time = $5/hr

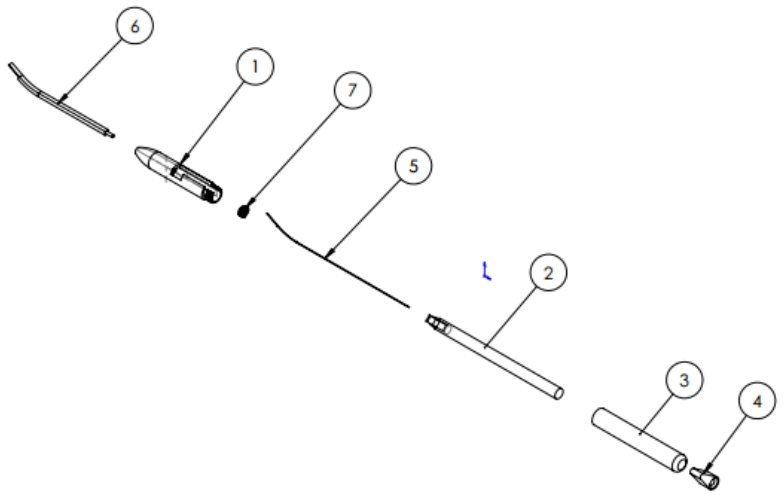
C_{op}^{prod} = cost/production time = $30/hr

Part	Part Name	QTY	Material	Processing	Price Per Unit
1	Handle Front	1	PEEK	Injection Molded	$3.5 [29]
2	Handle Actuator	1	PEEK	Injection Molded	$3.5 [29]
3	Handle Back	1	PEEK	Injection Molded	$3.5 [29]
4	Reset Button	1	PEEK	Injection Molded	$0.45 [29]
5	Stylet	1	304 Stainless Steel	OEM Component Supply CGWX-0170	$3.36 [26]
6	Tubing	1	304 Stainless Steel	Welded and Drawn	$3.50 [30]
7	Spring	1	Zinc-Plated Steel	OEM McMaster 9657K269	$0.88 [27]
				Total Material Cost	$18.69
				Tooling Cost (10,000 units)	$0.30
				Equipment Cost (5 year write-off time)	$0.01
				Overhead Cost	$0.23
				Total Cost per Part	$19.23

Table 3.1: Future material and machining costs

This design requires additional changes to the current paddle design. The paddle will have to be modified to contain a lamina on the top, which may need to be tested in the future for potential tissue ingrowth. This may end up being beneficial to allow the paddle to remain in place in the DRG space, but it could also make revisions more difficult. This surgical tool contains various orifices and apertures that may allow tissue and bodily fluid ingress, which makes it non-reusable for future surgical procedures. This would not be an issue as the tool would be included within the DRG paddle kit provided to the surgeons.

Appendix A. Engineering Drawings



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1	Handle Front		1
2	Handle Actuator		1
3	Handle Back		1
4	Reset Button		1
5	Stylet		1
6	Tubing		1
7	Spring		1

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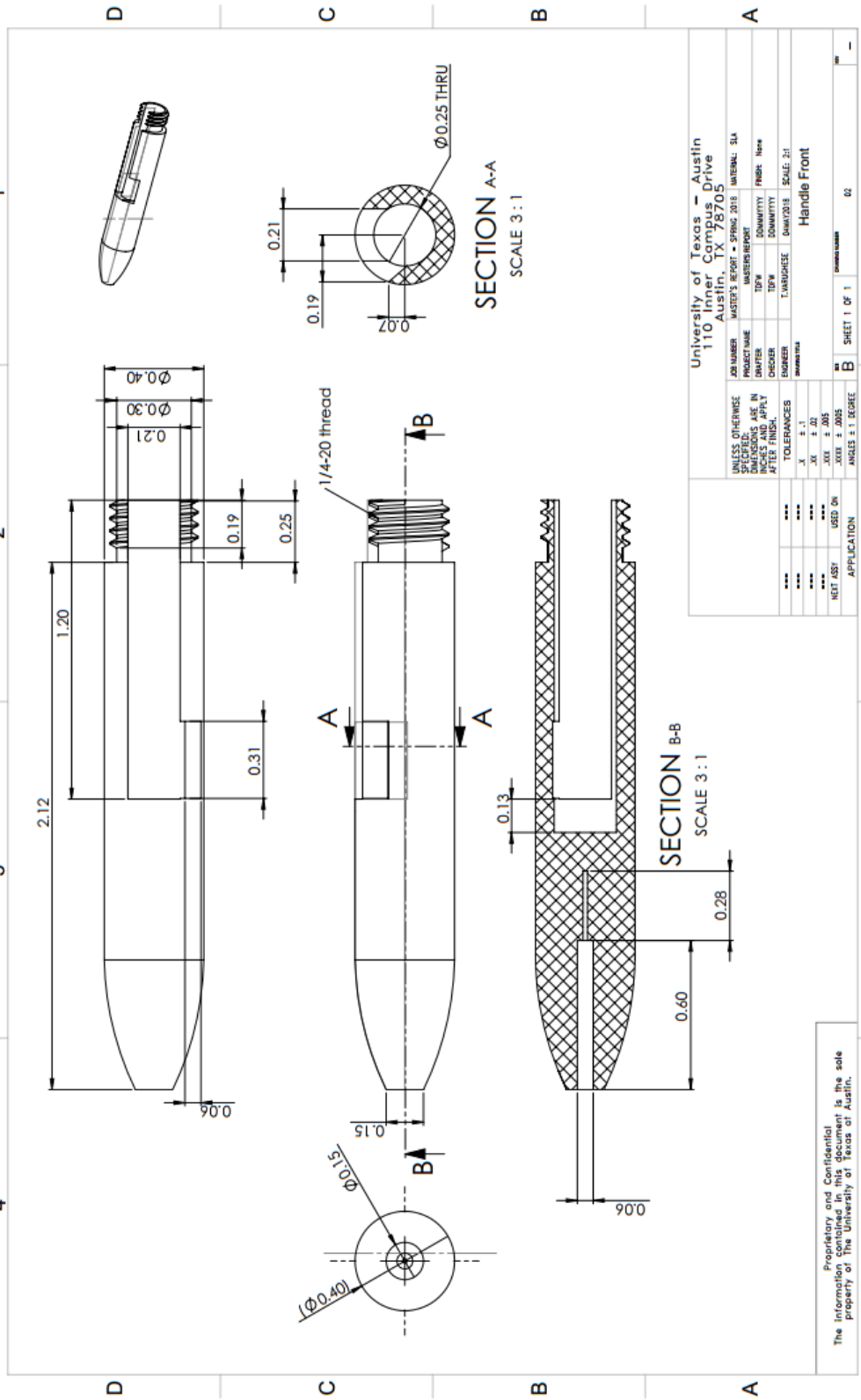
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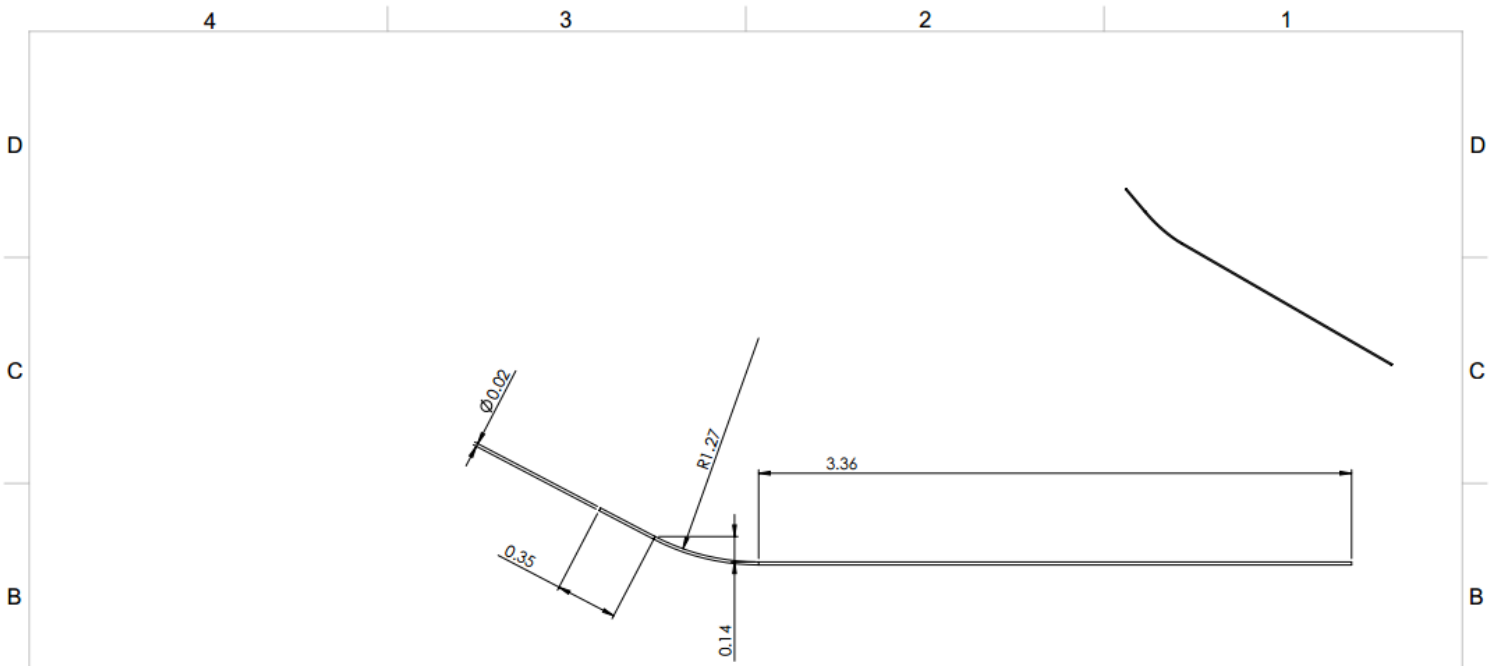

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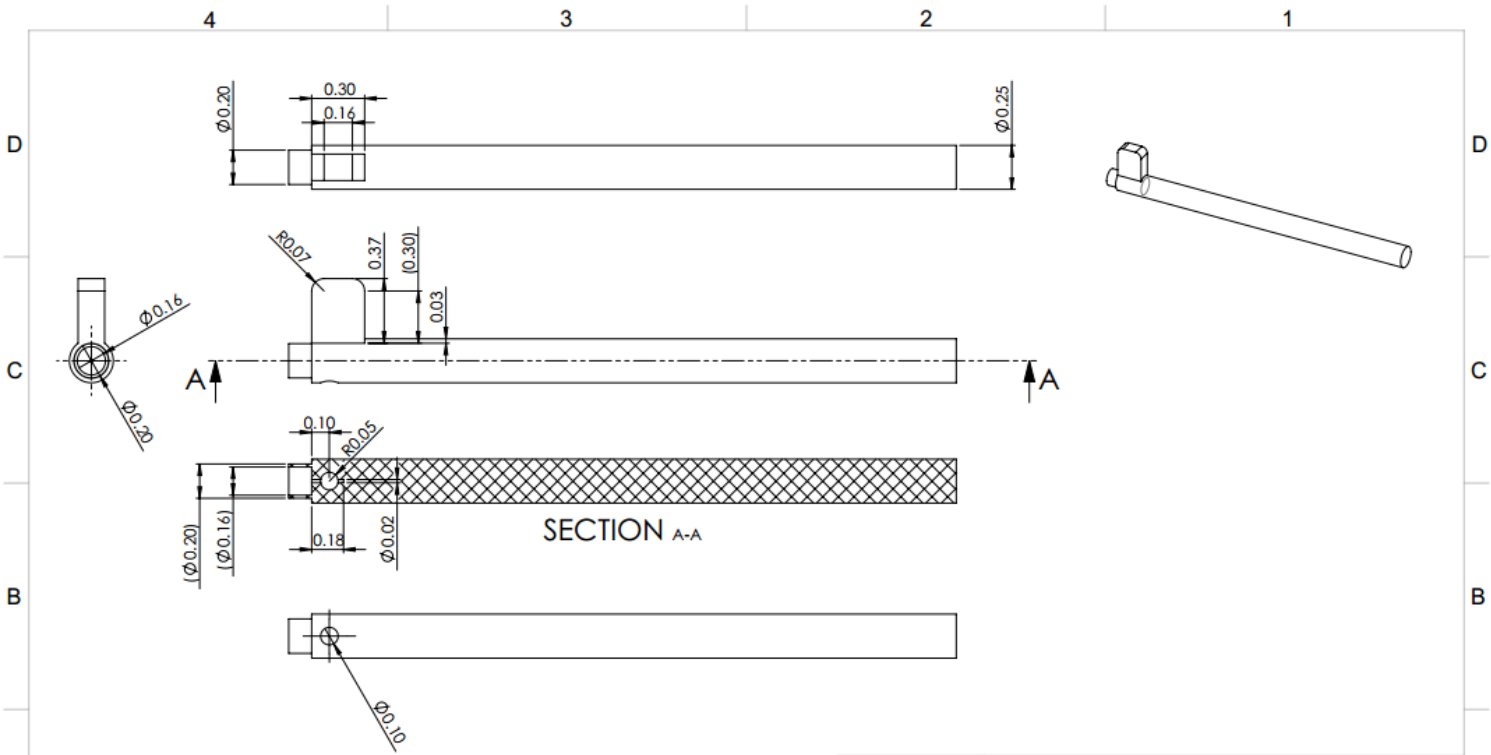
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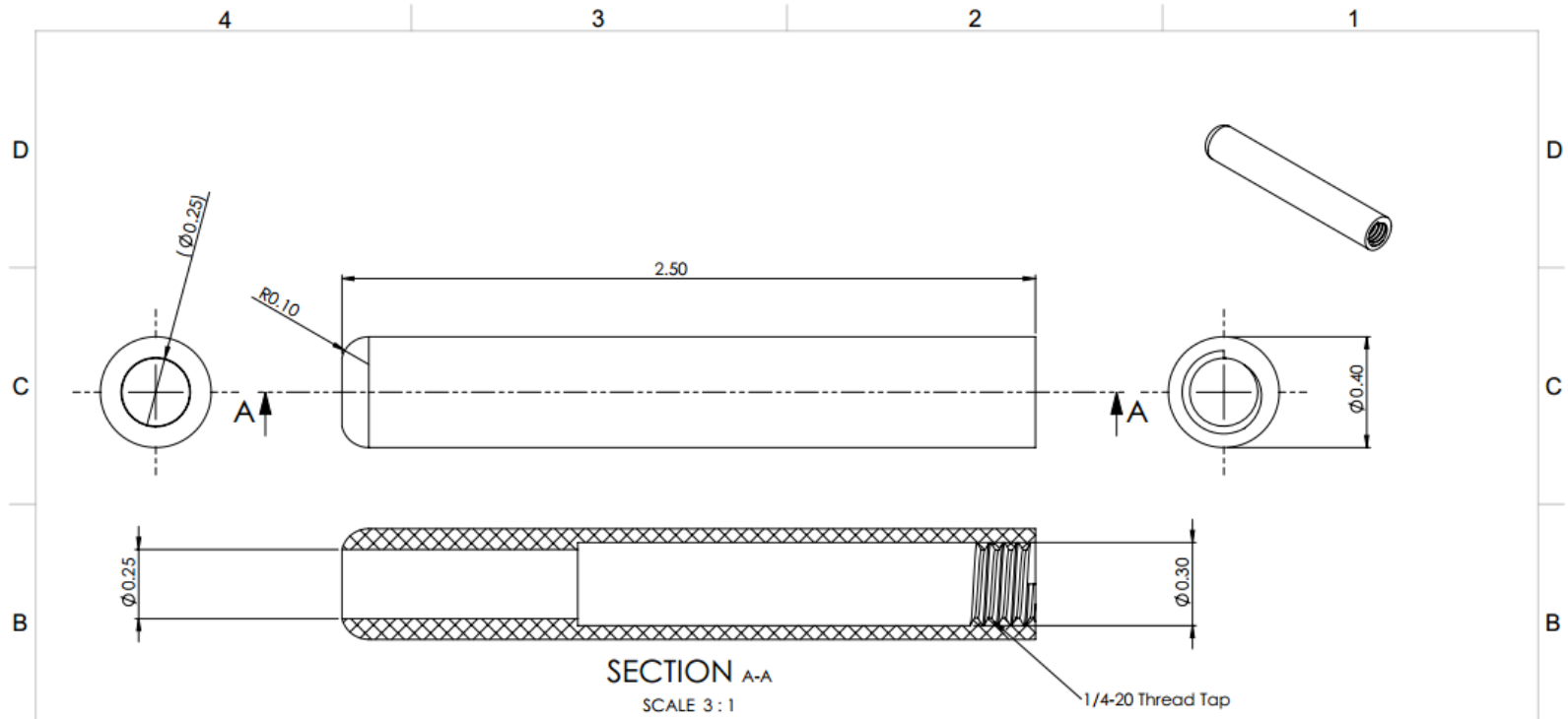
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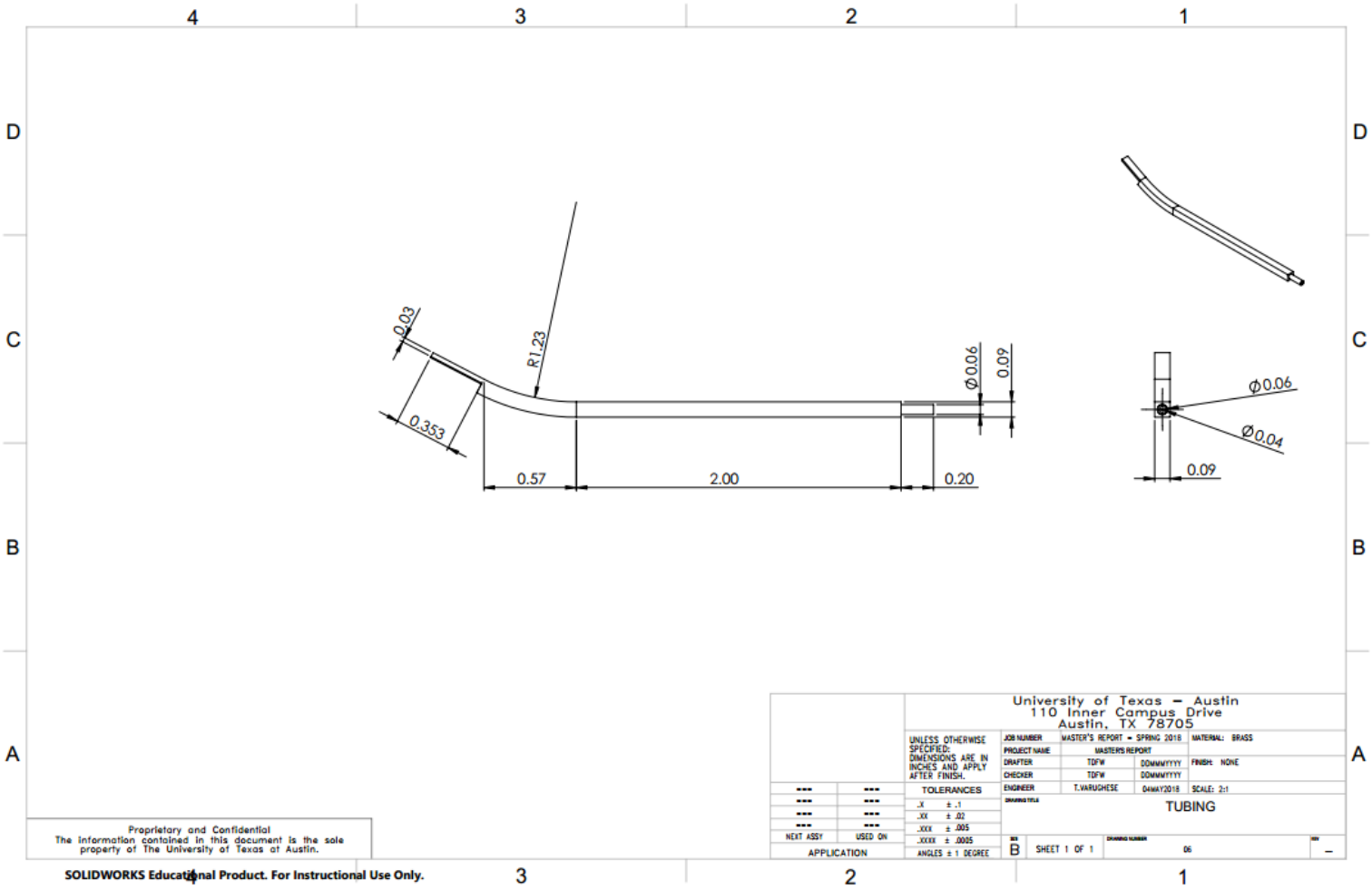
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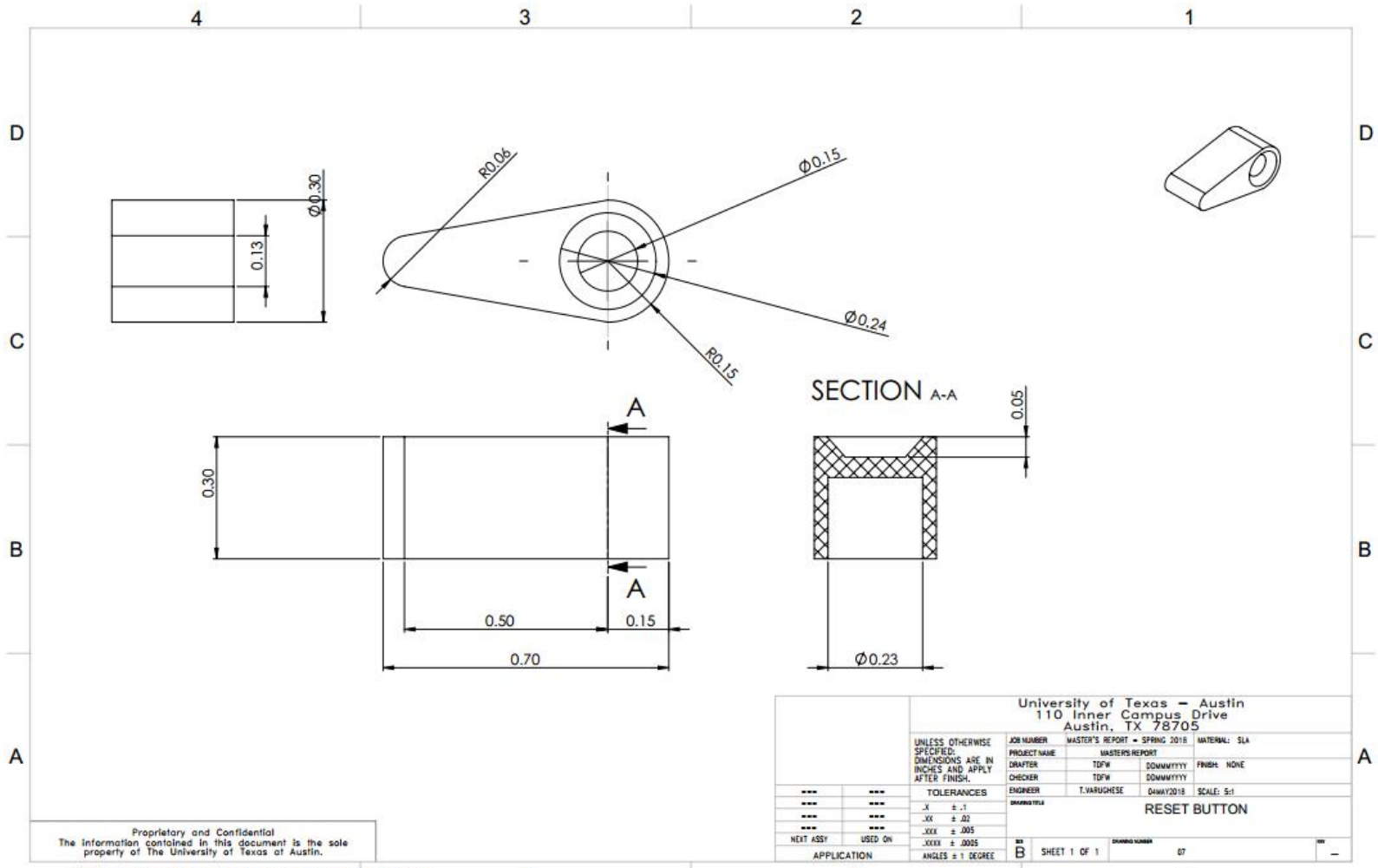
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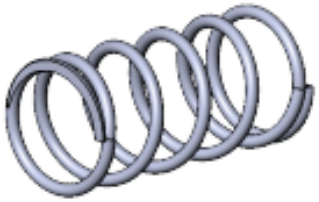

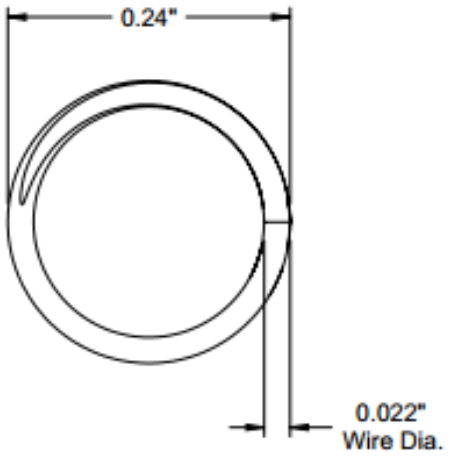

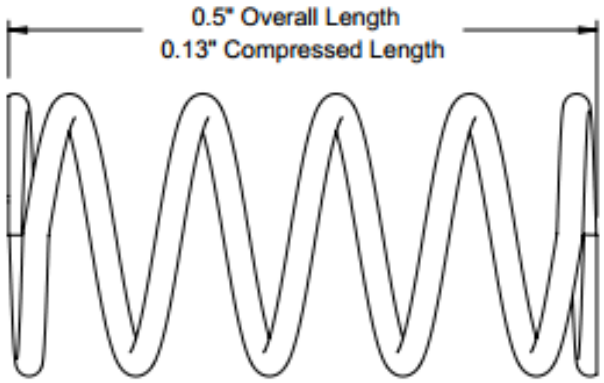

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PART NUMBER **9657K269**

Zinc-Plated Steel Music Wire Compression Spring

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